



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: HHS-OS-21524-60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary for Health, HHS.

ACTION: Notice.

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary, Department of Health and Human Services (HHS), announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0990-0278, which expires on June 30, 2014. Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on the ICR must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Submit your comments to [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or by calling (202) 690-6162.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or (202) 690-6162.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the document identifier HHS-OS-21524-60D for reference.

Information Collection Request Title: Federalwide Assurance Form – Extension OMB No. 0990-0278, Assistant Secretary for Health, Office for Human Research Protections.

**Abstract:** The Office for Human Research Protections is requesting a three year extension of the Federalwide Assurance (FWA). The FWA is designed to provide a simplified procedure for institutions engaged in HHS-conducted or supported research to satisfy the assurance requirements of Section 491(a) of the Public Health Service Act and HHS Regulations for the protection of human subjects at 45 CFR 46.103. The respondents are institutions engaged in human subjects research that is conducted or supported by HHS.

**Need and Proposed Use of the Information:** The information collected by OHRP through the FWA is the minimum necessary to satisfy the assurance requirements of the Public Health Service Act and the requirements of HHS regulations at 45 CFR 46.103.

**Likely Respondents:** Research institutions engaged in HHS-conducted or –supported research involving human subjects.

**Burden Statement:** The estimate of the hours per response assumes that virtually all respondents will complete the FWA form via the internet on an interactive page on the OHRP website. The time estimate includes an estimate of the time needed to (i) read and understand the instructions for completing the FWA; (ii) read and understand the FWA terms of assurance; and (iii) enter the information requested on the FWA form. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden - Hours

Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Federalwide Assurance (FWA)	11,050	2	30/60	11,050
Total				11,050

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Darius Taylor

Deputy, Information Collection Clearance Officer

Billing code: 4150-28

